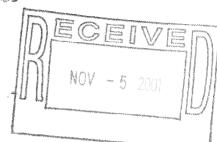


Innovative Nutrition Solutions

4384 '01 NOV 27 P1:35



October 24, 2001

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

<u>Flax Oil XTRA</u>: [For] healthy heart. Flax Oil has significant levels of alpha-linolenic acid, an essential fatty acid. Alpha-linolenic is converted to other beneficial omega-3 fatty acids which help promote healthy heart function.

<u>Co Q-10</u>, <u>Vitamin E</u>, <u>Hawthorn Berries [and] Garlic</u>: To further promote cardiovascular function and a healthy circulatory system...

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker, Esquire

Derock Shew Donk

Senior Vice President

Regulatory Affairs

Enclosure

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